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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/491,500 01/26/00 BLACK

K CEDAR043-453

EXAMINER

HM22/0705

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SORBELLO, F

ART UNIT

PAPER NUMBER

1633

DATE MAILED:

07/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/491,500

Applicant(s)

BLACK ET AL.

Examiner

Eleanor Sorbello

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 and 97-112 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-9, 11-26, 28-34, 97-100 and 104-109 is/are allowed.
- 6) ☒ Claim(s) 10, 27, 101-103 and 110-112 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

R sponds to amendment

1. Applicant's amendment and response to the official Office Action mailed December 20, 2000 (and filed as Paper No. 6), and Interview held on March 14, 2001 and filed as Paper No. 7, has been received and filed on March 26, 2001 as Paper No. 10C. Claims 1, 6, 18, 23 have been amended, and claims 110-112 have been added. Claims 1-34, 97-112 are pending. Applicant's amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's argument.
2. Applicant's arguments are addressed below on a per section basis. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 1, 10, 18, 27 and 105 are rejected under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 18 recite the phrase "simultaneously or substantially simultaneously". It is not clear what exactly is meant by the term "substantially". The claim needs to be amended to clarify and specifically point to that which was intended in the invention.

Claims 10, 27 105 recite the limitation "wherein the viral vector is an adenoviral vector," but the amended claims namely claims 6, 23 and 101, from which they depend do not recite viral vectors. There is no antecedent basis for viral vectors, and therefore the claims are rejected.

5. Claims 110, 111 and 112 are rejected under 35 U.S.C. 112, first paragraph for reasons of record. Applicant's arguments have been fully considered but they are not persuasive.

The newly added claims are directed to methods of delivery of pharmaceutical compositions to abnormal brain regions wherein the compositions delivered are viral vectors, expression vectors, oligonucleotides or nucleotide analogs. As such the instant application now falls in the realm of gene therapy, because the only reason one would deliver a viral vector or expression vector to an abnormal region of the brain is for treatment, by the transfer of a gene which expresses a protein. The instant application is therefore not enabled as applicants did not teach one how to make expression vectors or viral vectors comprising a gene or DNA of interest for delivery (using methods of delivery as taught by the instant invention) which results in treatment, except by prophetic consideration.

The nature of the invention is unpredictable as gene therapy per se is not enabled, although specific gene therapy applications are currently in clinical trials. Applicants state (See Amendment filed on March 26, 2001, page 6, paragraph 3) that applicants have deleted "DNA expression vectors", "viral vector", "oligonucleotide" and

Art Unit: 1633

"nucleotide analogs" from the Markush type language of claims 6, 23 and 101.


Applicants argue that the new claims 110-112 have supporting references showing that DNA expression vectors etc. were known at the time of filing of the instant specification and therefore delivery of expression vectors, viral vectors, oligonucleotide analogs should be enabled. However, examiner contends that applicants are not enabled for the delivery of DNA expression vectors, viral vectors, oligonucleotide and nucleotide analogs. This is made clear by the MPEP 608.01(p) where it states: "If the use disclosed is of such nature that the art is unaware of successful treatments with chemically analogous compounds, a more complete statement of how to use must be supplied...". As discussed above, the field of gene therapy (wherein the expression of a gene that is delivered is expected to express a protein), is not enabled in entirety as the field is unpredictable, because very often a gene that is delivered does not express the protein in adequate quantities to be useful, or that the expressed protein does not reach the specific point where its function is required. Therefore, applicants must document results indicating that the aforementioned vectors were delivered to art accepted models and the intended therapy observed. Therefore, in view of the broad claims drawn to delivery methods for the delivery of expression vectors, viral vectors, oligonucleotides and nucleotide analogs, the specification is not enabled.

Conclusion

6. Claims 1, 10, 18, 27, 101-103, 105, 110-112 stand rejected.
7. Claims 2-9, 11-17, 19-26, 28-34 are objected to as they depend from rejected claims. These claims would be allowable if rewritten to overcome the rejections under 35 U.S.C. 112 set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.
8. Any inquiry concerning this communication should be directed to Eleanor Sorbello, who can be reached at (703)-308-6043. The examiner can normally be reached on Mondays-Fridays from 6.30 a.m. to 3.00 p.m. EST.

Questions of formal matters can be directed to the patent analyst,
Tracey Johnson, whose telephone number is (703) 305-2982.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Clark, can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


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